Chairman Dingell at the Subcommittee on Oversight and Investigations hearing entitled "The Adequacy of the FDA Efforts to Assure the Safety of the Drug Supply Part II"

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS HEARING ENTITLED â€œTHE ADEQUACY OF THE FDA EFFORTS TO ASSURE THE SAFETY OF THE DRUG SUPPLY - PART IIâ€•
March 22,2007

Mr. Chairman, thank you for holding the second hearing in this Committeeâ€™s investigation of the handling of drug safety issues by the Food and Drug Administration (FDA). I welcome the FDA Commissioner, Dr. von Eschenbach, to the Committee.

The Commissioner should know that the FDAâ€™s response to this Committeeâ€™s inquiries has been less than acceptable. Responses have been slow to our document requests regarding food safety, drug safety, and conflicts of interest. We do intend to see that all of our questions are answered fully.

The Commissionerâ€™s appearance today was preceded a month ago by former FDA staff members who testified that they were forced to flee the FDA because they feared retaliation from their superiors. These are good doctors and scientists that exposed bad decisions -- decisions that appear to have needlessly cost American lives.

Both private statements and public quotes attributed to the Commissioner indicate that he does not tolerate public dissent from FDA employees. Private protests within the FDA do not appear to work either. For example, in the case of the drug Ketek, only after Congress was informed by FDA former employees of the confused dictates of senior FDA officials did the Agency finally rectify its mistakes. We have heard testimony that the Commissioner told these same employees that anyone not willing to be a â€œteam playerâ€• would be traded.

Given that their protests went to Congressional offices, including this Committee, I must remind the Commissioner that threatening FDA employees with retaliation for talking to Congress is not only unacceptable, it is illegal. My concern is echoed in a letter dated March 9, 2007, from Senator Chuck Grassley to Commissioner von Eschenbach, which I believe my colleagues should review. I ask that the letter be placed in the hearing record.

Dr. von Eschenbach has been invited to tell us why the Agencyâ€™s new Drug Safety Initiative will adequately address the â€œcultural problemsâ€• identified by a number of experts on FDA drug safety policies. That â€œculturalâ€• problem comes do what Senator Grassley calls having grown â€œtoo cozyâ€• with industry â€“ preferring drug approvals over swift action when cle safety signals manifest post-market problems.

At our last hearing, Dr. David Graham framed the question for todayâ€™s hearing as â€œWhat in the FDA proposals would prevent another Vioxx?â€•

For example, what in the new FDA proposal would ensure that FDA reviewers would not negotiate for more than 14 months on label changes, even after receiving substantial evidence of serious cardiac side effects as they apparently did with Vioxx?

Would the newly proposed Office of New Drugs act any differently upon the clear warnings regarding Vioxx from the epidemiological work performed in the Office of Drug Safety?

Under the new proposal, would the FDA medical officers in the Anti-Infectives Division been allowed to present their findings to the Advisory Committee?

Under the new proposal, are the Advisory Committees more likely to hear about potential fraud or errors in pivotal safety studies?

Moreover, where in the new FDA proposal is there any provision to fully inform the public of the case risks and benefits prior to a drugâ€™s approval?

I, for one, do not see anything in the new FDA proposal that effectively responds to the many problems identified by this Committee over the last few years. None of these â€œreformsâ€• impose structural guarantees to stop the cultural bias that has skewed the Agencyâ€™s judgment.

In the end, what the Administration proposal really boils down to is â€œtrust us.â€• That would be easier to accept if the FDA and the Department of Health and Human Services were not resisting Congressional oversight and threatening whistle blowers.

Regardless, drug safety continues to be the central concern of this Committee as the reauthorization of the Prescription Drug User Fee Act (PUDUFA) goes forward. And you can trust us that, with the strong support of my colleagues across the aisle, we will come up with legislative changes to ensure against another Vioxx.

I thank both Chairman Stupak and Ranking Member Whitfield for holding this hearing, and I look forward to the testimony of todayâ€™s witnesses.

- 30 -

(Contact: Jodi Seth, 202-225-2927)

Prepared by the Committee on Energy and Commerce
2125 Rayburn House Office Building, Washington, DC 20515